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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/567,879

04/16/2007

Karl-Hermann Schlingensiepen

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08/11/2009

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EXAMINER

GIBBS, TERRA C

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

08/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,879

Applicant(s)

SCHLINGENSIEPEN ET AL.

Examiner

TERRA C. GIBBS

Art Unit

1635

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 12-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-11, and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission mailed on June 22, 2009 has been entered.

Claims 1-17 are pending in the instant application.

Claims 7 and 12-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely made the restriction (election) requirement in the reply filed on September 22, 2008. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant is reminded that the Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Accordingly, claims 1-6, 8-11, and 15-17 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed December 23, 2008, claims 1, 4-6, 8-11, and 15-17 were rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/65928 A2. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed December 23, 2008.

Response to Arguments

In response to this rejection, Applicants argue that SEQ ID NO:5894 as disclosed in WO 99/65928 is not SEQ ID NO:1, nor is it a fragment thereof. Applicants contend that SEQ ID NO:5894 is a 10 base sequence, and the Examiner is applying it as a 9 base sequence. Applicants contend that the Examiner has removed the terminal C of

SEQ ID NO:5894 prior to comparing it to Applicant's SEQ ID NO:1 and is thus comparing a fragment of SEQ ID NO:5894 and not the complete sequence. Therefore, Applicants argue that SEQ ID NO:5894 cannot anticipate Applicant's SEQ ID NO:1 or a fragment thereof.

These arguments and contentions have been fully considered, but are not found persuasive because the claims are drawn to:

An antisense oligonucleotide selected from the group consisting of the sequence 5'- TTG CAT AAA CCC AAG GAG -3' (SEQ ID NO:1) and modifications thereof, and a fragment thereof having at least 8 nucleotides of the sequence 5'- TTG CAT AAA CCC AAG GAG -3' (SEQ ID NO:1) and modifications thereof.

Applicants argue that SEQ ID NO:5894 as disclosed in WO 99/65928 is not SEQ ID NO:1, nor is it a fragment thereof. However, Applicants should note that the claims are not drawn to just a fragment of SEQ ID NO:1, but instead are drawn to a fragment thereof having at least 8 nucleotides of the sequence 5'- TTG CAT AAA CCC AAG GAG -3' (SEQ ID NO:1). SEQ ID NO:5894 as disclosed in WO 99/65928 is obviously a fragment thereof having at least 8 nucleotides of the sequence SEQ ID NO:1.

While it is acknowledged that SEQ ID NO:5894 as disclosed in WO 99/65928 is a 10 basepair sequence, it is also acknowledged that 9 basepair of SEQ ID NO:357682 constitute a fragment having at least 8 nucleotides of SEQ ID NO:1 of Applicant's invention.

Therefore, SEQ ID NO:5894 as disclosed in WO 99/65928 is a fragment having at least 8 nucleotides of the sequence 5'- TTG CAT **AAA CCC AAG** GAG -3' (SEQ ID

NO:1). See the bold area which is the fragment of SEQ ID NO:5894 having at least 8 nucleotides of SEQ ID NO:1 of Applicant's invention.

Therefore, WO 99/65928 anticipates claims 1, 4-6, 8-11, and 15-17.

In the previous Office Action mailed December 23, 2008, claims 1, 5, 6, 8, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 01/77384 A2. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed December 23, 2008.

Response to Arguments

In response to this rejection, Applicants argue that SEQ ID NO:357682 as disclosed in WO 01/77384 is not SEQ ID NO:1, nor is it a fragment thereof. Applicants contend that SEQ ID NO:357682 is a 12 base sequence, and the Examiner is applying it as an 11 base sequence. Applicants contend that the Examiner has removed the terminal A of SEQ ID NO:357682 prior to comparing it to Applicant's SEQ ID NO:1 and is thus comparing a fragment of SEQ ID NO:357682 and not the complete sequence. Therefore, Applicants argue that SEQ ID NO:357682 cannot anticipate Applicant's SEQ ID NO:1 or a fragment thereof.

These arguments and contentions have been fully considered, but are not found persuasive because Applicant is reminded of the claim language as recited above.

Applicants argue that SEQ ID NO:357682 as disclosed in WO 01/77384 is not SEQ ID NO:1, nor is it a fragment thereof. As noted above, the claims are not drawn to just a fragment of SEQ ID NO:1, but instead are drawn to a fragment thereof having at least 8 nucleotides of the sequence 5'- TTG CAT AAA CCC AAG GAG -3' (SEQ ID NO:1). SEQ ID NO:357682 as disclosed in WO 01/77384 is obviously a fragment thereof having at least 8 nucleotides of the sequence SEQ ID NO:1.

While it is acknowledged that SEQ ID NO:357682 as disclosed in WO 01/77384 is a 12 basepair sequence, it is also acknowledged that 11 basepair of SEQ ID NO:357682 constitute a fragment having at least 8 nucleotides of SEQ ID NO:1 of Applicant's invention.

Therefore, SEQ ID NO:357682 as disclosed in WO 01/77384 is a fragment having at least 8 nucleotides of the sequence 5'- TTG **CAT AAA CCC AAG** GAG -3' (SEQ ID NO:1). See the bold area which is the fragment of SEQ ID NO:357682 having at least 8 nucleotides of SEQ ID NO:1 of Applicant's invention.

Therefore, WO 01/77384 anticipates claims 1, 5, 6, 8, and 15-17.

Claim Rejections - 35 USC § 103

In the previous Office Action mailed December 23, 2008, claims 1-3 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/65928 A2 (Reference A.M on Applicant's Information Disclosure Statement filed February 9, 2006) in view of WO 01/68122 (Reference A.L on Applicant's Information Disclosure

Statement filed February 9, 2006). **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed December 23, 2008.

Response to Arguments

In response to this rejection, Applicants argue that the WO 99/65928 contains a 10 base sequence and there is no teaching, suggestion, or motivation for a person of ordinary skill in the art to remove the terminal C of SEQ ID NO:5894. Applicants also argue that WO 01/68122 does not cure the deficiencies of WO 99/65928 at least because WO 01/68122 is cited for modifications of SEQ ID NO:1, not SEQ ID NO:1 itself.

These arguments have been fully considered but are not found persuasive because as noted above, the claims are drawn to a fragment having at least 8 nucleotides of the sequence 5'- TTG CAT **AAA CCC AAG** GAG -3' (SEQ ID NO:1). SEQ ID NO:5894 as disclosed in WO 99/65928 is obviously a fragment thereof having at least 8 nucleotides of the sequence SEQ ID NO:1. See the bold area which is the fragment of SEQ ID NO:5894 having at least 8 nucleotides of SEQ ID NO:1 of Applicant's invention.

While it is acknowledged that SEQ ID NO:5894 as disclosed in WO 99/65928 is a 10 basepair sequence, it is also acknowledged that 9 basepair of SEQ ID NO:357682 constitute a fragment having at least 8 nucleotides of SEQ ID NO:1 of Applicant's invention.

WO 01/68122 was relied upon to provide motivation to one of ordinary skill in the art to modify the antisense oligonucleotide disclosed by WO 99/65928 to enhance cellular uptake, enhance affinity for nucleic acid target, and increase stability in the presence of nucleases.

In view of the foregoing, after consideration of all the evidence and facts, the totality of the rebuttal evidence of non-obviousness fails to outweigh the evidence of obviousness made of record. Thus, it is maintained that the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was filed.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached from 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James "Doug" Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Terra Cotta Gibbs/
August 8, 2009